

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Attachment 1In the specification:

Please replace the first paragraph on page 42 as follows:

-- Metformin hydrochloride (502.5g) was mixed with sodium carboxymethylcellulose (Blanose 7HF) (50g) for five minutes in a small planetary mixer and sufficient purified water added with continued mixing to produce a damp granular mass. The wet granulation was dried at 60°C for 1 hour and then size reduced in a hammer mill. The granulation was dry blended with a mixture prepared from 358g [385g] of hydroxypropylmethylcellulose 2208 USP (100,000 cps grade), 10g of hydroxypropylmethylcellulose 2910 USP (5 cps grade) and 102g of microcrystalline cellulose in a planetary mixer for 10 minutes. Finally this mix was lubricated by mixing with 1% w/w magnesium stearate and compressed into capsule shaped tablets, each containing 0.5g of metformin hydrochloride. When tested for in vitro release of metformin the following results were obtained.--